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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/755,125

01/09/2004

Leslie Joe Dunaway

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EXAMINER

HUYNH, CARLIC K

ART UNIT

PAPER NUMBER

1617

MAIL DATE

DELIVERY MODE

08/31/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/755,125	Applicant(s) DUNAWAY, LESLIE JOE	
	Examiner Carlic K. Huynh	Art Unit 1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 20 June 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-26 is/are pending in the application.
 4a) Of the above claim(s) 7-15, 25 and 26 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6 and 16-24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>09 January 2004</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of the Claims

1. Claims 1-26 are pending in the application, with claims 25-26 having been withdrawn in response to the restriction requirement submitted on May 21, 2007. Accordingly, claims 1-24 are being examined on the merits herein.

Election/Restrictions

2. Applicant's election with traverse of the claims of Group I, namely claims 1-24, in the reply filed on June 20, 2007 is acknowledged. The traversal is on the ground(s) that there is no search burden when searching methods for treating a recited disease comprising the administration of the compounds of the claims of Group II.

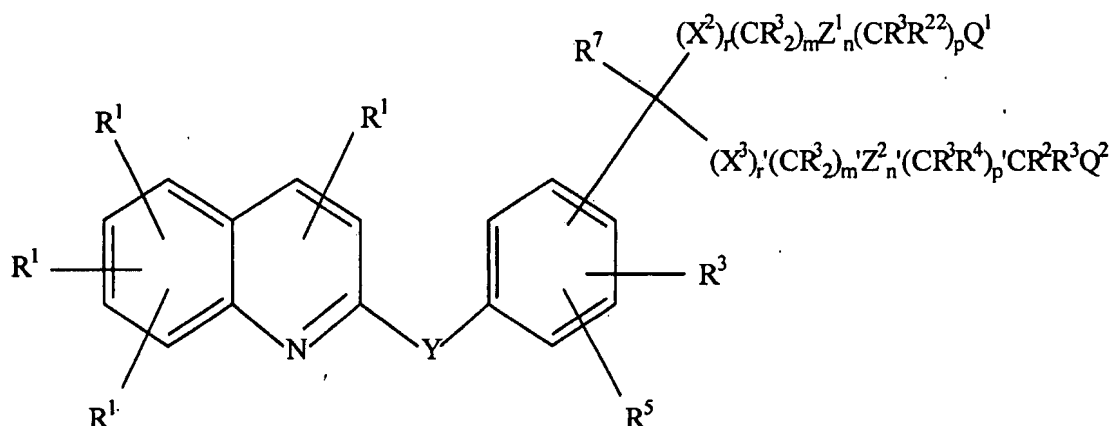
Applicants' arguments were not found persuasive. The arguments were not found persuasive because many products can be used with the process of Group I and thus the search for the products of Group II will not necessarily yield the process of Group II. Furthermore, if the product claims of Group II are found allowable, then the process claims of Group II will be rejoined. In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104, as per *In re Ochiai*.

Claims 24-25 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim.

Election was made with traverse in the reply filed on June 20, 2007.

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3. Applicants' election with traverse of 1-(((1(R-(3-(2-(7-chloro-2-quinolinyl)ethenyl)phenyl)-3-(2-(2-hydroxy-2-propyl)phenyl)propyl)thio)methyl)cyclopropaneacetic acid as a compound of formula:



in the reply filed on June 20, 2007 is acknowledged. Because Applicants did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

A telephone call to the Applicants representative, R. Andrew Patty, on August 8, 2007 was placed to inform the Applicant of an election of species of a disease or neuronal inflammatory condition. Applicants have elected with traverse graying of scalp hair. Because Applicants did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). Affirmation of this election must be made by applicant in replying to this Office action.

Claims 7-15 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Election was made without traverse in the reply filed on June 12, 2007 and in a telephone call placed on August 8, 2007.

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Accordingly, claims 1-6 and 16-24 are examined on the merits herein.

The restriction requirement and the election of species requirement are still deemed proper and is made FINAL.

Information Disclosure Statement

The Information Disclosure Statement submitted on January 9, 2004 is acknowledged.

Specification

4. The use of the trademarks Singulair®, Zivirax®, and Famvir® has been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 1-6 and 16-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over

DeLong et al. (US 2006/0247214) as evidenced by O'Byrne (Chest, 1997, Vol.111, No. 2

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Supplement, pp 27S-34S), in view of Pizzichini et al. (European Respiratory Journal, 1999, Vol. 14, pp. 12-18) as evidenced by SINGULAIR® product information (Merck & Co, Inc., April 2007, pp. 1-19).

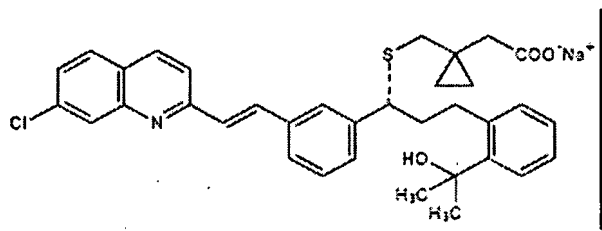
DeLong et al. teach a method for reversing hair graying in mammals comprising administering nonsteroidal anti-inflammatories such as cyclooxygenase or lipoxygenase inhibitors (page 13, paragraph [0110]; and page 14, paragraph [0131]).

As evidenced by O'Byrne, lipoxygenase inhibitors block the production of leukotrienes as a means to control allergic and inflammatory diseases such as asthma (abstract and page 28S, figure 1). Thus, the inhibition of leukotrienes may be used to reduce the inflammatory response.

DeLong et al. do not teach 1-(((1(R-(3-(2-(7-chloro-2-quinolinyl)ethenyl)phenyl)-3-(2-(2-hydroxy-2-propyl)phenyl)propyl)thio)methyl) cyclopropaneacetic acid.

Pizzichini et al. teach a cyeteinyl leukotriene₁ (CysLT₁) receptor antagonist, montelukast, can be used to treat allergic and inflammatory diseases such as asthma (abstract). Thus the inflammatory response may be reduced by using antagonists to leukotrienes.

As evidenced by SINGULAIR® product information from Merck & Co, Inc., montelukast has the chemical formula of,



and has the chemical name of 1-(((1(R-(3-(2-(7-chloro-2-quinolinyl)ethenyl)phenyl)-3-(2-(2-hydroxy-2-propyl)phenyl)propyl)thio)methyl) cyclopropaneacetic acid, which is the same

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compound as the elected compound of 1-(((1(R-(3-(2-(7-chloro-2-quinoliny)ethenyl)phenyl)-3-(2-(2-hydroxy-2-propyl)phenyl)propyl)thio)methyl) cyclopropaneacetic acid (page 1).

Since DeLong et al. teach lipoxxygenase inhibitors that control an inflammatory condition such as asthma can also be used to reverse hair graying, and since Pizzichini et al. teach the leukotriene antagonist montelukast can control an inflammatory condition such as asthma, it would obvious to one in the art that montelukast can also be used to reverse hair graying.

Accordingly, absence the showing of unexpected results, it would have been obvious to a person of skill in the art at the time of the invention to employ the lipoxygase inhibitor composition of DeLong et al. to contain montelukast because the compound of Pizzichini et al. is montelukast and according to Pizzichini et al., montelukast can be used to control asthma and thus reverse hair graying.

The motivation to combine the lipoxxygenase composition of DeLong et al. to the montelukast composition of Pizzichini et al. is that Pizzichini et al. teach montelukast can be used to control asthma and thus reverse hair graying.

It is noted that "It is obvious to combine individual compositions taught to have the same utility to form a new composition for the very same purpose" and "It is obvious to combine two compositions taught by the prior art to be useful for the same purpose to form a third composition that is to be used for the very same purpose". *In re Kerkhoven*, 626 F.2d 846, 205 U.S.P.Q. 1069 (C.C.P.A. 1980).

Conclusion

6. No claims are allowable.

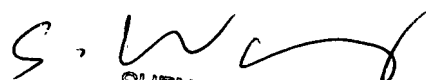
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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carlic K. Huynh whose telephone number is 571-272-5574. The examiner can normally be reached on Monday to Friday, 8:30AM to 5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

ckh


SHENGJUN WANG
PRIMARY EXAMINER